

DISCUSSION OF THE AMENDMENT

An Abstract has been added.

Claims 2, 3, 5, 11, 16, 17 and 19 have been amended by inserting the term --by weight--. While this term does not explicitly appear in the specification, it is implicitly supported by corresponding disclosure of WO 03/002517 (Bromine Compounds) (discussed in greater detail *infra*) that is described in the specification of an analogous process using concentrations of ammonia and acid expressed in terms of weight percent, and the fact that percentage amounts in an aqueous solution would be recognized herein by persons skilled in the art as --by weight--.

Superfluous terms such as “comprised” and “generally utilized” have been deleted, where appropriate. The term “ammonia” has been replaced with --  $\text{NH}_3$  -- for purposes of consistency.

New Claims 26 and 27 have been added, as supported in the specification at page 5, lines 22-23.

No new matter is believed to have been added by the above amendment. Claims 1-27 are now pending in the application.

REMARKS

The rejection of Claims 1-25 under 35 U.S.C. § 103(a) as unpatentable over CN 1297885 (Fan et al)<sup>1</sup> in view of Bromine Compounds, and in further view of US 3,007,940 (Shavel et al), is respectfully traversed.

Both Fan et al and Bromine Compounds have been described in the specification herein. Thus, as noted by the Examiner, Fan et al requires a minimum reaction temperature for the amination of 1,1-cyclohexanediactic acid anhydride with aqueous ammonia of from 30 to 110°C, and Bromine Compounds requires such amination be carried out in a molar ratio of ammonia/anhydride of between 5 and 10 and at a temperature below 20°C. Thus, Fan et al and Bromine Compounds each disclose the same reaction under two sets of mutually exclusive conditions, respectively. Absent the present disclosure as a guide, there would have been no reason to modify either of Fan et al or Bromine Compounds, since neither would appear to be problematical, and moreover, reaction temperature and ammonia/anhydride molar ratio would appear to be dependent on each other. In other words, Fan et al discloses a lower molar ratio but a higher temperature, compared to Bromine Compounds. The Examiner has simply engaged in picking and choosing temperatures and ratios which support the Examiner's position, while ignoring temperatures and ratios that teach away from the present invention.

Claim 9 and claims dependent thereon are separately patentable, because none of the applied prior art discloses or suggests such a regime.

In addition, Claims 13, 14, 24 and 25 are separately patentable, because Shavel et al discloses the transformation of 1,1-cyclohexanediactic acid into the corresponding anhydride on a steam bath (column 4, lines 40-45), and thus, not in the presence of an organic solvent.

---

<sup>1</sup> Applicants believe that the publication number for Fan et al, rather than its application number, is the more accurate citation.

Finally, new Claims 26 and 27 are separately patentable, since Bromine Compounds requires a crystallization step after formation of the 1,1-cyclohexanediactic acid monoamide. As described in the specification herein at page 5, lines 22-23, an advantage over Bromine Compounds is the lack of a need to crystallize the 1,1-cyclohexanediactic acid monoamide prior to further reaction thereof in the subsequent steps for producing gabapentin.

In sum, the combined prior art neither discloses nor suggests the advantages flowing from the non-obvious combination of parameters according to the present invention, i.e., low temperature combined with low NH<sub>3</sub>/anhydride molar ratio:

- High yields;
- High purity (low NH<sub>3</sub> content which is important for the quality of the so-obtained gabapentin;
- No required crystallization step;
- No scraps;
- Reaction conditions suitable for industrial manufacture.

For all the above reasons, it is respectfully requested that this rejection be withdrawn.

The rejection of Claims 2, 3, 5, 6, 7, 11, 16, 17, 19, 20 and 21 under 35 U.S.C. § 112, second paragraph, is respectfully traversed. As discussed above under "Discussion of the Amendment," the term --by weight-- has been inserted where applicable. With regard to Claims 6, 7, 20 and 21, these claims already recite that the ratio is a molar ratio.

For all the above reasons, it is respectfully requested that this rejection be withdrawn.

Regarding paragraph 1 of the Office Action, a new Abstract has been added.

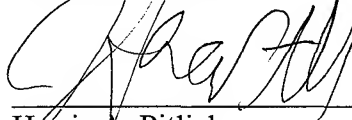
Application No. 10/578,783  
Reply to Office Action of September 5, 2007

All of the presently-pending claims in this application are now believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

Norman F. Oblon



Harris A. Pitlick

Registration No. 38,779

Customer Number

**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 08/07)

NFO:HAP\la